

REMARKS

I. Status of the Claims

Claims 1, 3, 4, 6, 7, 12, 15, 17, 18, 22, 105-109, and 111-115 are amended to insert SEQ ID NOs. No new matter is introduced.

II. Claim Rejections

A. Obviousness-Type of Double Patenting

In the Final Office Action of April 8, 2005, and the Advisory Action of October 12, 2005, the Examiner maintained the rejection of claims 5 and 19 under the judicially created doctrine of obviousness-type of double patenting, alleging that these two claims are unpatentable over claims 1-3 of U.S. Patent No. 6,592,877 ("the '877 patent"). Applicants respectfully traverse the rejection.

The subject matter of claims 1-3 of the '877 patent is an isolated fusion protein comprising four *M. tuberculosis* antigens: TbRa3 (SEQ ID NO:77), Tb38-1 (SEQ ID NO:88), **TbH4** (SEQ ID NO:89), and 38kD (SEQ ID NO:155). In contrast, claim 5 of the present application is directed to a composition that contains a fusion protein comprising *M. tuberculosis* antigens MTb81 and Mo2, as well as TbRa3, 38kD, Tb38-1, and **FL TbH4** (SEQ ID NO:12). Claim 19 is directed to a composition that contains a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), **FL TbH4**, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α -crystalline, and 85 complex.

The Examiner apparently took the position that since claims 5 and 19 of the present application both relate to a fusion protein comprising *M. tuberculosis* antigens TbRa3, 38kD, Tb38-1, and **FL TbH4**, they are obvious in light of claims 1-3 of the '877 patent that relate to a fusion protein comprising antigens TbRa3, Tb38-1, 38kD, and **TbH4**. Applicants do not agree. This is because *M. tuberculosis* antigens FL TbH4 and TbH4 are significantly

different from each other not only in length but also in the amino acid sequence. Contrary to what the names of these two antigens might suggest, FL TbH4 is not a full length sequence or a longer sequence that encompasses the sequence of TbH4. In fact, TbH4 has 166 amino acids and FL TbH4 has 286 amino acids, and there is a mere 16% homology between the two sequences. See sequence alignment result attached as Exhibit A.

Thus, Applicants contend that the fusion protein recited in claim 5 or 19 is not obvious over claims 1-3 of the '877 patent. As such, the withdrawal of the obviousness-type double patenting rejection is respectfully requested.

B. 35 U.S.C. §112, Second Paragraph

In the Final Office Action and Advisory Action, the Examiner maintained the rejection of claim 6 under 35 U.S.C. §112, second paragraph, for its dependency from a rejected base claim. As discussed above, the only other outstanding rejection, the obviousness-type double patenting rejection, has been fully addressed. The rejection of claim 6 is therefore obviated.

Appl. No. 09/688,672
Amdt. dated December 12, 2005
Reply to Office Action of April 8, 2005 and Advisory
Action of October 12, 2005

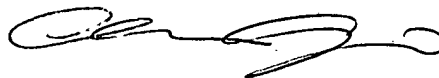
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachments (Exhibit A: sequence alignment between SEQ ID NO:12 of the present application and SEQ ID NO:89 of U.S. Patent No. 6,592,877)

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